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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------------|---------------------|------------------|
| 09/884,629 | 06/19/2001 | Peter H. St. George-Hyslop | 1034/IJ800US1 | 3866 |

7590 09/23/2004
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New York, NY 10022

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| EXAMINER |
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WOITACH, JOSEPH T

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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|--------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/884,629 | ST. GEORGE-HYSLOP ET AL. | |
| | Examiner | Art Unit | |
| | Joseph T. Voitach | 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 8-23 and 29-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application filed June 19, 2001, claims benefit to provisional application 60/212,534, filed June 20, 2000.

Applicants amendment filed June 14, 2004 has been received and entered. The specification has been amended. Claims 6 and 7 have been amended. Claims 1-35 are pending.

Election/Restriction

Applicant's election with traverse of Group I, claims 1-7, 24-28, filed February 21, 2003, in Paper No. 9 was acknowledged. No new arguments have been provided, therefore the restriction is maintained for the reasons of record. The requirement is still deemed proper and is therefore FINAL.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Claims 1-35 are pending. Claims 8-23, 29-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9. Claims 1-7, 24-28 are currently under examination as they are drawn to a transgenic non-human mammal whose genome comprises a polynucleotide that encodes an amyloid precursor protein 695 transgene wherein the protein produced has the specific mutations in residues 670, 671 and 717 of APP₆₉₅.

Specification

The disclosure objected to because it has a Brief Description of the Drawings (page 7) and makes reference to figure 1 in other parts of the specification (see page 12, line 9 for example) but no figures were filed with the instant disclosure (see transmittal letter, section 4, filed June 19, 2001) is withdrawn.

The amendment to the specification to remove specific reference to the figures has obviated the basis of the objection. Since no figure was previously presented the removal of the specific recitations describing them does not constitute new matter. Further, the amendments to the specification to remove reference to the figures in discussion of the specific results, while apparently less informative absent the figures is sufficient to stand alone.

Information Disclosure Statement

It was noted that the listing of references in the specification is not a proper information disclosure statement (citing 37 CFR 1.98(b) and MPEP § 609 A(1)) states

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Applicants have acknowledged the requirement, however have not provides an IDS or copy of the cited references.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 24-28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

With respect to claims 1 and 24 being vague and unclear in the recitation of “a heterologous amyloid precursor protein 695 (APP₆₉₅) polypeptide” Examiner agrees that the given the terms plain meaning the claims would be considered definite, in particular in light of the fact that it is in reference to a transgene present in the mammal.

With respect to claim 6 being unclear in the recitation of “accelerated” the amendment to recite a specific time has obviated the basis of the rejection.

With respect to claim 7 being vague and unclear because the claim appears to encompass any transgenic mouse, as long as the mouse was part of its ancestry, the amendment to indicate that the transgene is present has addressed the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 4-7, 24, 25, 27 and 28 rejected under 35 U.S.C. 102(a/e) as being anticipated by Sato *et al.* (US Patent 6,037,521) is withdrawn.

Upon re-examination of the teachings of Sato *et al.* Examiner agrees that while multiple APP alterations are taught and contemplated, the specific teaching for the 717 mutation recited and encompassed by the instant claims is not taught by Sato *et al.*

Claims 1, 2, 4-7, 24, 25, 27 and 28 stand rejected under 35 U.S.C. 102(e) as being anticipated by Sommer *et al.* (US Patent publication 2001/0016951 A1).

Claims 1, 2, 4-7 and 24- 28 stand rejected under 35 U.S.C. 102(e) as being anticipated by Hsiao *et al.* (US Patent 6,509,515).

Applicants argue that neither of the references specifically teach to use the Indian mutation V717F in APP. See Applicants' amendment, top of page 19. Applicants' arguments have been fully considered, but not found persuasive.

Review of Sommer *et al.* clearly teaches that the V717F mutation was known at the time of filing (paragraph 003) and teaches that transgenic mice expressing mutated forms of APP, specifically that human APP sequences containing mutations at 670/671 and 717 were operatively linked to neuron-specific promoters for expression in transgenic mice (paragraph 004), and that mice comprising all two or three or more alterations are contemplated (paragraph

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16). Similarly, review of Hsiao *et al.* indicates that all three mutations were known in the prior art and contemplated for use in generating transgenes for use transgenic models (see for example figure 2). Applicants do not argue that any other embodiments are not taught only that each of the references fail to teach the 717 mutation. However, as discussed above this is not found persuasive because each of the cited reference teaches that this APP mutation was known and contemplated for use in generating transgenic animal models of Alzheimer's Disease.

Conclusion

No claim is allowed.

As indicated previously, claim 3 is free of the art of record because while the art provides various genetic backgrounds for the resulting transgenic mice produced, none specifically teach any specific reason to generate (C3H xC57BL6) x C57 cross.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

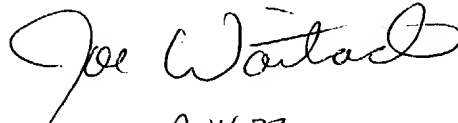
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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